



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of : M. K. CERRETA et al. ) Art Unit: 1654  
Serial No. : 10/809,597 ) Examiner: Andrew D. Kosar  
Confirmation No. : 1495  
Filed : 03/25/2004  
For : Crystalline Phases of a Potent HCV Inhibitor  
Docket No. : 9/266

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

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on March 3, 2005

By: *Philip I. Datlow*  
Philip I. Datlow  
Reg. No. 41,482

**DECLARATION OF VIDA GORYS UNDER 37 CFR 1.132**

Sir:

I, Vida Gorys, declare and state as follows:

1. I am a trained chemist having received a B.Sc. degree in Chemistry from McGill University, Montreal, Qc, Canada, in 1978. I have been employed at Boehringer Ingelheim (Canada) Ltd. since 1988, first as a Research Assistant II, and since 1991 as a Research Associate I. My general duties include organic compound synthesis.

2. In my capacity as Research Associate I at Boehringer Ingelheim (Canada) Ltd., I synthesized the compound designated as compound #822 in U.S. Patent No. 6,608,027 B1 and the corresponding WO 00/59929 A1 according to the procedure of Example 34C in these

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**Declaration of Vida Gorys**

two references. As indicated in Example 34C, this is the same procedure as is described in Example 34 of these references but reacting bromoketone 34f with commercially available N-iso-propylthiourea. I synthesized compound #822 according to this described procedure with the following minor modifications:

Step C: The cyclopentyl chloroformate reagent used in this step was not prepared as described, but this time the commercially available material was used.

Step G: At the end of this step we purified the compound obtained using column chromatography and used the less pure fractions for Step H.

The final product compound obtained using this slightly modified process is identical to the compound obtained using the process of Example 34C in these references.

3. The final product compound prepared as described above was then sent to John Smoliga at Boehringer Ingelheim Pharmaceuticals, Inc., for testing and evaluation.

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: February 28, 2005

By: Vida Gorys  
Vida Gorys



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By:   
Philip I. Datlow  
Reg. No. 41,482

**DECLARATION OF JOHN SMOLIGA UNDER 37 CFR 1.132**

Sir:

I, John A. Smoliga, declare and state as follows:

1. I am a trained solid-state chemist having received a Bachelor of Arts degree in Earth Science/Geology from Kean University in 1977, a Master of Arts degree in Geology/Geochemistry from Western Connecticut State University in 1985 and my Ph. D. in Chemical Microscopy from McCrone Research Institute in 1993, working with Dr. Walter C. McCrone. I have over 28 years of experience in solid-state characterization including x-ray powder diffraction analysis. I joined Boehringer Ingelheim Pharmaceuticals, Inc. in Ridgefield, CT in 1996 as a Senior Scientist in the Analytical

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**Declaration of John A. Smoliga**

Sciences Department. I am currently a Principal Scientist, responsible for solid-state characterization within the Analytical Sciences Department.

2. I am a co-inventor of the invention described and claimed in the above identified application and I am familiar with the Office Action dated November 3, 2004, in that application.

3. In my capacity as Principal Scientist within the Analytical Sciences Department at Boehringer Ingelheim Pharmaceuticals, Inc., I tested and evaluated the compound that was prepared by Vida Gorys as described in her Declaration filed herewith to determine if said compound was a crystalline material.

4. I subject said compound to an X-ray powder diffraction (XRPD) analysis according to the following procedure:

X-ray powder diffraction analyses were conducted on a Bruker AXS X-Ray Powder Diffractometer Model D8 Advance, available from Bruker AXS, Inc. of Madison, WI, using CuK $\alpha$  radiation. The instrument is equipped with a long fine focus x-ray tube. The tube power was set to 40kV and 30mA. The instrument was operated in parallel beam mode with a Gobel Mirror, using a 0.6mm exit slit, a 0.4° soller slit, a LiF flat crystal diffracted beam monochromator and a NaI scintillation detector. A detector scan was run using a tube angle of 1° 2 $\theta$ . Step scans were run from 2 to 35° 2 $\theta$ , at 0.05° per step, 4 sec per step. A reference quartz standard was used to check instrument alignment. Samples were prepared for analysis by filing a zero background quartz holder.

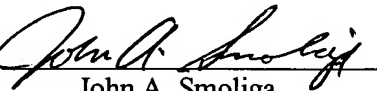
5. The diffraction pattern obtained for this compound is shown in the attached Figure 1. This diffraction pattern shows a broad halo indicating that this compound is an amorphous, non-crystalline material.

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made

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are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 2/28/05

By:   
John A. Smoliga